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“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

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IS 12721-2 (2005): Dental Base Metal Casting Alloys, Part 2: Nickel - Based Alloys [MHD 8: Dentistry]



“ज्ञान से एक नये भारत का निर्माण”

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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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(पहला पुनरीक्षण)

Indian Standard
DENTAL BASE METAL CASTING ALLOYS
PART 2 NICKEL-BASED ALLOYS
(*First Revision*)

ICS 11.060.10

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NATIONAL FOREWORD

This Indian Standard (Part 2) (First Revision) which is identical with ISO 6871-2 : 1994 'Dental base metal casting alloys — Part 2 : Nickel-based alloys' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of the Dentistry Sectional Committee (MGP 47) and approval of the Medical Instruments, General and Production Engineering Division Council.

IS 12721 : 1989 'Dental materials — Base metal casting alloys — Specification' which was published earlier was based on ISO 6871 : 1987 'Dental base metal casting alloys'. In view of technological developments at the national and International levels ISO 6871 has been revised and published in two parts. The first revision of IS 12721 has been undertaken to incorporate the medication effected in two parts of ISO 6871 brought out in 1994 and to be published in two parts. This Indian Standard (Part 2) is identical with ISO 6871-2 : 1994 and the other part is as follow:

Part 1 Cobalt-based alloys

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this standard, but it recommended that, in assessing possible biological or toxicological hazards, reference should be made to IS 12572 (Part 1) : 1994 'Biological evaluation of medical devices: Part 1 Guidance on selection of tests (*first revision*)' and IS 12572 (Part 10) : 1988 'Guide for evaluation of medical devices for biological hazards: Part 10 Methods of biological testing and evaluation of dental materials'.

For other compositions the manufacturer has to present adequate evidence of biological investigations in accordance with IS 12572 (Part 1) or IS 12572 (Part 10) and/or clinical investigations in order to assess the biological response of the material.

For specific quantitative requirements of corrosion resistance and amount of metal ions leached from the alloy, reference should be made to static immersion test, described in Annex A.

Beryllium is considered to be hazardous in handling unless adequate precaution are met. Annex B contains those recommended precaution.

Annex A form an integral part of this standard. Annexes B and C are for information only.

The text of the ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker in the International Standard while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their places are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 6892 : 1998 Metallic materials — Tensile testing at ambient temperature	IS 1608 : 1995 Mechanical testing of metals — Tensile testing (<i>second revision</i>)	Technically equivalent

Indian Standard
DENTAL BASE METAL CASTING ALLOYS
PART 2 NICKEL-BASED ALLOYS
(First Revision)

1 Scope

This part of ISO 6871 specifies requirements and test methods for nickel-based dental casting alloys suitable for use in fabrication of removable dental appliances. It does not apply to alloys intended for use in fabrication of metal-ceramic dental restorations.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 6871. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 6871 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

ISO 6892:1984, *Metallic materials — Tensile testing*.

ASTM-B 600-74, *Recommended practice for descaling and cleaning titanium and titanium alloy surfaces*.

3 Definitions

For the purposes of this part of ISO 6871, the following definitions apply.

3.1 alloy: Metallic substance consisting of a mixture of the basic metallic element (the element predominating by mass) and other elements such as alloying elements and impurities.

3.2 alloying element: Metallic or non-metallic elements added to or retained by a basic metal for the purpose of giving that metal certain special properties.

3.3 impurity: Metallic or non-metallic elements present but which are not intentionally added to or retained by a metal.

3.4 casting alloy: Alloy primarily intended for the production of castings.

3.5 base metal casting alloy: Casting alloy in which cobalt or nickel is the basic metallic element.

3.6 nickel-based dental casting alloy: Dental casting alloy in which nickel is the constituent present in the highest percentage by mass (main constituent).

4 Requirements

4.1 Composition

The chemical composition of the casting alloy shall meet the following requirements:

Nickel	main constituent
Chromium	not less than 20 % (m/m)
Molybdenum	not less than 4 % (m/m)
Nickel + Cobalt + Chromium	not less than 85 % (m/m)

If the alloy contains beryllium, the beryllium content shall not exceed 2 % (m/m).

Constituents of the alloy in excess of 20 % (m/m) shall be within 2 % (m/m) of the value stated [see clause 8b) and 9.2d)]. Constituents in excess of 2 % (m/m) but not in excess of 20 % (m/m) shall be within 1 % (m/m) of the value stated [see clause 8b) and 9.2d)].

Other compositions with nickel as the basic metallic element may be permissible subject to approval by regulatory authorities (see the Introduction). For such alloys, all alloying elements with more than 0,1 % (m/m) shall be given on the package or in the accompanying literature.

4.2 Biocompatibility

See the Introduction for guidance on biocompatibility.

4.3 Corrosion resistance

See the Introduction for guidance on corrosion resistance.

Testing shall be in accordance with annex A. The total of the mean aggregate quantity of ions released shall be reported as specified in A.3.

4.4 Mechanical properties

When tested in accordance with 7.3 and 7.4, the mechanical properties of the alloy shall comply with table 1.

Table 1 — Mechanical properties

Proof stress of non-proportional elongation, $R_{p0,2}$	Percentage elongation after fracture
MPa	%
min.	min.
500	3,0

5 Sampling

The sample shall be adequate to prepare the specimens required for 6.2 and A.1, and shall be from one batch.

Further sample and packaging shall be made available for visual inspection and analytical procedures in accordance with 7.1 and 7.2.

6 Preparation of test specimens

6.1 General

Prepare the test specimens by the lost wax process of investment casting generally used in a dental laboratory, following the manufacturer's instructions for use.

Cleanly separate the test specimens from sprues, freed of casting beads, parting lines and surface impurities and then grit blast the specimens.

Replace any test specimens with visible defects.

6.2 Specimens for mechanical properties

Prepare six test specimens in accordance with figure 1 or 2.

Dimensions in millimetres

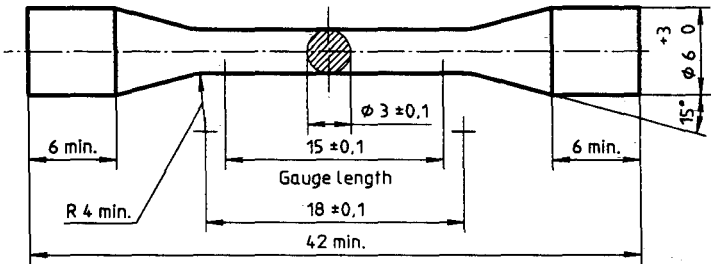


Figure 1 — Test specimen with conical shoulders

Dimensions in millimetres

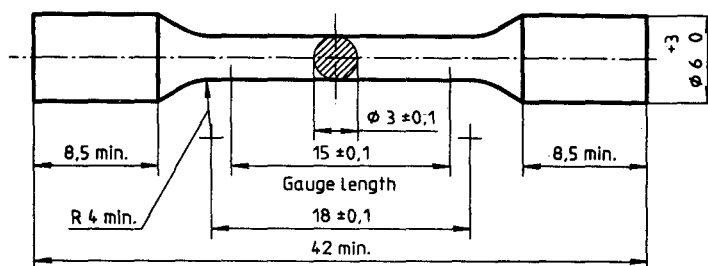


Figure 2 — Test specimen with radius shoulders

7 Testing

7.1 Visual inspection

Visually inspect the specimens to check that the requirements specified in clauses 8 and 9 have been met.

7.2 Analytical procedures

Recognized analytical procedures shall be used in determining the composition (ISO methods where these exist).

7.3 Proof stress of non-proportional elongation

Determine the 0,2 % proof stress of non-proportional elongation in accordance with ISO 6892 on test specimens (see 6.2), cast and conditioned in accordance with 6.1. Load the test specimens in a universal mechanical testing instrument at a cross-head speed of $(1,5 \pm 0,5) \text{ mm min}^{-1}$ up to the fracture point of the specimen.

If less than four specimens comply with the requirements in table 1, take another full set of specimens and repeat the test. If less than four specimens of the new set comply, reject the alloy.

For reporting calculate the value for proof stress as the mean of the values from those four, five or six specimens of the one set which are found to comply with the requirements in table 1.

7.4 Percentage elongation after fracture

Determine the percentage elongation after fracture in accordance with ISO 6892.

If less than four specimens comply with the requirements in table 1, take another full set of specimens

and repeat the test. If less than four specimens of the new set comply, reject the alloy.

For reporting calculate the value for elongation as the mean of the values from those four, five or six specimens of the one set which are found to comply with the requirements in table 1.

At least four of these specimens shall also comply with the proof stress requirement in table 1.

8 Information and instructions

The following information shall be in the package or be supplied with it:

- the alloy's intended use given in unambiguous language;
- a list of all the elements present and their percentage concentration (m/m) if present in concentrations equal to or greater than 2 %;
- density in grams per cubic centimetre;
- 0,2 % proof stress in megapascals;
- modulus of elasticity in gigapascals;
- percentage elongation after fracture;
- Vickers hardness;
- solidus and liquidus temperatures (melting range) in degrees Celsius;
- processing instructions.

As the alloy contains nickel or if the alloy contains more than 0,02 % (m/m) of beryllium or other hazardous elements, this shall be clearly stated on the package, and adequately detailed instructions regard-

ing precautions shall be given in the package or accompanying literature.

9 Marking

9.1 Casting ingots

The casting ingots or other forms in which the alloys are supplied shall be clearly marked to identify the alloy. Dental casting alloys in accordance with this part of ISO 6871 shall be supplied in a form and size suitable for crucibles in a dental investment casting process and in a stable container.

9.2 Packaging

The packaging shall be clearly labelled with the following information:

- a) the manufacturer's and/or distributor's name and address;
- b) trade- or brand-name of the alloy;
- c) the alloy's intended use given in unambiguous language;
- d) the three principal constituents of the alloy and their percentage by mass;
- e) batch number: each package shall be provided with a serial number or letter/number combination related to the manufacturer's records for the particular batch which shall permit positive identification;
- f) net mass in grams;
- g) a **WARNING** that the alloy contains nickel and if it contains more than 0,02 % (m/m) beryllium or any other hazardous elements. The warning shall also name the elements and state the percentage by mass in which they are present.

Annex A

(normative)

Static immersion test

In order to get information of the kind and amount of metal ions leached from the alloy, the following specimens, reagents and procedure shall be applied.

A.1 Specimens

Prepare two sets of three specimens, each with dimensions of 32 mm × 10 mm × 1,5 mm.

Prepare the test specimens by the lost wax process of investment casting generally used in a dental laboratory, following the manufacturer's instructions for use.

Cleanly separate the test specimens from sprues, freed of casting beads, parting lines and surface impurities.

Grit blast, then wet grind using standard metallographic procedure to ASTM-B 600 or FEPA P 1200 silicon carbide paper. Remove at least 0,1 mm from all sides. Clean away any residual abrasive.

Replace any test specimens with visible defects.

A.2 Reagents

Lactic acid	C ₃ H ₆ O ₃ analytical grade
Sodium chloride	NaCl analytical grade
Water	Grade 2 of ISO 3696

A.3 Procedure

Prepare the surface of the test specimens as speci-

fied in A.1 and measure the surface area of the specimens to the nearest 0,1 cm².

Clean away any abrasive, oil or grease. Rinse the specimens in ethanol or methanol, and dry.

Divide the specimens in two sets of three, each set having a total surface of approximately 20 cm². Prepare an aqueous solution comprising 0,1 mol/l lactic acid and 0,1 mol/l sodium chloride.

Select containers so as to avoid adsorption of trace elements on the surface of the container and that the volume of solution will be approximately 1,3 ml cm² of the test specimen surface area.

Suspend each set of three test specimens hanging on nylon threads in a separate container for 7 days at (37 ± 1) °C in a manner such that all specimens are completely covered by the test solution and do not come into contact with each other or the wall or the bottom of the container. Most appropriate is a triangular arrangement of the samples in the container. Tightly seal the container to prevent evaporation.

Analyse each test solution separately for elements listed in clause 8b) using an adequately sensitive, quantitative analytical method, e.g. AAS (atomic absorption spectrometry) or OES (optical emission spectrometry). For each of the two tests, report the values of each element present in micrograms per square centimetre in accordance with national regulations.

NOTE 1 When an International Standard for corrosion testing becomes available, the test solution and procedures given above will be revised in conformity with that International Standard.

Annex B

(informative)

Recommendations for handling alloys containing beryllium

Adequate local exhaust ventilation should be provided for all operations such as casting, grinding, polishing and finishing, where beryllium-containing alloys are handled, and dusts and fumes can be generated. Exhaust air should not be recirculated back into the work area.

Adequate general ventilation should be provided for all areas where beryllium-containing alloys are handled.

Warning signs should be placed in areas where dust from beryllium-containing alloys can be generated.

Clean protective clothing, which is changed at frequent intervals, should be used by each operator working with beryllium-containing alloys.

Dust removal from clothing and the cleaning of machinery should be accomplished by power suction methods only.

To prevent dust becoming airborne, compressed air should not be used in areas where beryllium-containing alloys are being handled.

Every person exposed to the hazards of beryllium-containing alloys has to be informed of the health hazard information according to legal requirements and to the proper handling procedures and the precautions to be taken.

Annex C

(informative)

Bibliography

- [1] ISO 1942-2:1989, *Dental vocabulary — Part 2: Dental materials.*
- [2] ISO/TR 7405:1984, *Biological evaluation of dental materials.*
- [3] ISO/TR 10271:1993, *Dentistry — Determination of tarnish and corrosion of metals and alloys.*
- [4] ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

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<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ASTM-B 600-74 : 1991 Recommended practice for descaling and cleaning titanium and titanium alloy surfaces	IS 12828 : 1989 Recommended practice for descaling and cleaning titanium and titanium alloy surfaces	Identical

The Technical Committee responsible for the preparation of this standard has reviewed the provisions of the following International Standard and has decided that the same is acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO 3696 : 1987	Water for analytical laboratory use — Specification and test methods

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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